

PATENT
USSN 10/054,611
Docket 002970US; 018/182c

REMARKS

This paper is responsive to the Office Action dated January 5, 2004 (Paper No. 5), which is the first action on the merits of the application.

Claims 1-34 were previously pending in the application. Claims 23-34 were withdrawn. The other claims were examined and stand variously rejected. Upon entry of this Amendment, certain claims are amended, and claims 35-46 are added. The added claims are methods of identifying or detecting an hTERT nucleic acid in a sample, and depend from claims in the elected group. Accordingly, the new fall within the group under examination. All together, claims 1-22 and 35-46 are now pending in the application and under examination.

Further consideration and allowance of the application is respectfully requested.

Interview Summary:

The undersigned wishes to express his gratitude to Examiner Malgorzata Walicka and Examiner Rebecca Prouty for the courtesy of a helpful and productive interview at the Patent Office on March 11, 2004. The rejections of record were discussed, and the undersigned proposed certain amendments to the claims. Suggestions made by the Examiners are incorporated into this response.

Information Disclosure Statements:

Applicants have not received initialed copies of the PTO-1449 that accompanied each Information Disclosure Statement filed in this application before the most recent Office Action. In addition, Supplemental Information Disclosure Statement was filed on January 16, 2004, subsequent to the Office Action.

Applicants request full consideration and acknowledgement of the information provided in all of the IDSes filed in this application. Copies of each PTO-1449 is enclosed with this response for the convenience of the Examiner.

Amendments:

Claims 1, 13, and 14 have been amended in a manner that is believed to overcome the objections made in section 2.4 of the Office Action.

Entry of these and the other amendments to the claims does not introduce new matter into the disclosure. Support for the new claims may be found at various places in the specification, and the

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claims as previously presented. Stringent hybridization conditions (claims 1, 13, 35, and 41) are taken from paragraphs [0124], [0125], and [0126] of the application as published. Identifying cDNA or mRNA (claims 4 and 19) is supported by claims 29 and 30 as originally presented. New claims 36-38 and 42-44 are supported by claims 4, 9, and 10. Use of the claimed identifying and detecting methods in determining or assessing tumors (claims 39-40 and 45-46) is supported in the specification *inter alia* in paragraphs [0013], [0196], and [0224] to [0229].

The specification has been amended in the manner suggested in Section 2.2 of the Office Action. Applicants are grateful to Examiner Walicka for providing an opportunity to make these corrections.

The priority paragraph has been amended to drop the claim of priority to previous application 08/724,643, filed Oct. 1, 1996. The statement regarding incorporation by reference has been deleted, to align the present disclosure with that of parent application USSN 09/843,676. Incorporation of the previous applications by reference is not needed for the present disclosure to meet the patentability requirements of 35 USC § 101, 102, 103, and 112.

Formal drawings will be provided in a separate submission.

Election of group for examination:

Applicants hereby confirm election of Group I (claims 1-22 and 35-46) for examination on the merits in this application, without traverse.

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Request for Rejoinder:

Claims 23-34 have been amended to depend from and incorporate limitations of claims in the elected group. Specifically, claim 23 covers *amplification primers for use in the detection method of claim 14*. Claim 27 covers a PCR product *formed while undertaking detection method of claim 14*. Claim 28 covers a hybridization complex *formed while undertaking the detection method of claim 2*.

Furthermore, the claimed probes and primers in claims 23-28 have been amended to match those of the method claims from which they depend.

Thus, the prior art sequence search is based on SEQ. ID NO:224 for all the claims. Utility of the products of claims 23-36 is demonstrated by the method claims from which they depend. Upon determination that the claims of Group I are described and enabled by the specification, it follows that the claims of Groups II, III, and IV will also be enabled.

Accordingly, all of the claims can be examined together with the elected group without raising substantive new issues under 35 USC §§ 101, 102, 103, or 112. To save applicants the financial burden and delay of having to file divisional applications for all the groups, applicants respectfully request that all the claims be rejoined into the group under examination.

Rejections under 35 USC § 112:

Claims 1-22 stand rejected under § 112 ¶ 1, as being broader than what is described and enabled by the specification as filed.

Applicants respectfully disagree. The skilled reader will understand by what is provided in the specification, in combination with standard methodology for performing hybridization and amplification reactions at the time the priority application was filed, that the inventors had possession of the previously claimed invention, and would be able to implement working embodiments within the scope of the claimed genus without undue experimentation.

Furthermore, the amended claims fulfill all the requirements of § 112 as follows:

- Independent claim 1 defines the probe used in the hybridization method as an hTERT polynucleotide or homolog according to its ability to hybridize to the prototype sequence (SEQ. ID NO:224) under explicit hybridization conditions. The procedure indicates that the probe hybridizes to the target nucleic acid *specifically*, which it is able to do due to its explicit hybridization properties. Accordingly, the method can be implemented by the skilled reader without undue experimentation.

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- Independent claim 2 defines the probe used in the hybridization method as *consisting essentially of 25 or more consecutive nucleotides from the hTERT encoding region of SEQ. ID NO:224*. This means that the probe has 25 or more consecutive nucleotides of SEQ. ID NO:224 (up to the full length of the hTERT encoding region), and may also have additional nucleotides, providing that the additional nucleotides do not substantially diminish the ability of the nucleotides taken from SEQ. ID NO:224 to hybridize with a target hTERT nucleic acid in a specific fashion.
- Independent claim 13 defines the primer used in the amplification method according to its ability to hybridize to the prototype sequence (SEQ. ID NO:224) under explicit conditions. The procedure indicates that the primer amplifies the target nucleic acid *specifically*, which it is able to do due to its explicit hybridization properties.
- Independent claim 14 defines each of the primers in the combination used for the amplification method as *consisting essentially of 15 or more consecutive nucleotides from the hTERT encoding region of SEQ. ID NO:224*. This means that each primer has 15 or more consecutive nucleotides of SEQ. ID NO:224, and may also have additional nucleotides, providing that the additional nucleotides do not substantially diminish the ability of the nucleotides taken from SEQ. ID NO:224 to specifically amplify a target hTERT nucleic acid.
- The other claims all depend from and incorporate the limitations of these four independent claims.

Claims 1 and 2 also stand rejected under 35 USC § 112 ¶ 2 for not specifying the hybridization conditions used.

The hybridization conditions are now explicitly stated in claim 1, as being part of the definition of the probe structure. The probe of claim 2 is defined according to the number of consecutive nucleotides of SEQ. ID NO:224 it contains. Accordingly, claim 2 need not recite particular hybridization conditions in order to comply with § 112 ¶ 2.

Withdrawal of these rejections is respectfully requested.

Rejections under 35 USC § 103

The claims under examination stand rejected under § 103 as being obvious over Adams et al., (Nature 377:3-174, 1995; and GenBank accession AA311750) and/or GenBank accession AA281296

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(Straussberg et al.). The Office Action suggests that [while the function of the prior art EST sequences is not indicated,] one skilled in the art knows that EST sequences are created to be used for detecting a presence of the sequences that are homologous to them.

Applicants respectfully disagree. There were hundreds of thousands of human sequences and sequence fragments in GenBank at the time the priority application was filed. There was no motivation to use an unannotated EST sequence to probe or amplify an unannotated gene when there were so many other sequences present in GenBank with demonstrated function and interest.

Furthermore, each of the claims pending in this application has a feature that cannot be practiced using the sequence data alone, without knowledge that the sequence encodes hTERT. Claims 1 and 13 both include as a step in the procedure where the user *explicitly identifies the nucleic acid as encoding hTERT or a fragment thereof* if a hybrid or amplification product is detected. Claims 2 and 14 are both explicit methods for determining *whether a sample encodes hTERT or an hTERT fragment*. This requirement breathes life and meaning into the rest of the procedure that ensues.

None of the cited references disclose the sequences as encoding hTERT or an hTERT fragment. Accordingly, without the information provided in the present application, it would be impossible for someone reading the Adams or Straussberg disclosures to practice the invention as claimed.

Withdrawal of this rejection is respectfully requested.

Request for Interview

Applicants respectfully request that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

In the event the Examiner determines that there are other matters to be addressed, applicants hereby request an interview by telephone.

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Fees Due

Enclosed with this Amendment is authorization to charge the Deposit Account for the new claims and the extension of time.

Should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, applicants hereby petition for such relief, and authorize the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,



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